REMARKS

Applicants respectfully request reconsideration of the present Application. Claims 1, 12-15, 17-23, and 29 have been amended and claim 5 has been canceled herein. Care has been exercised to introduce no new matter. Claims 1-4, 6-15, 17-25, and 29-34 are pending and are in condition for allowance.

Rejections based on 35 U.S.C. § 112

Claims 12-15, 17-25 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Applicants have amended independent claims 12 and 23 to more clearly point out and distinctly claim the subject matter regarded as the invention. Accordingly, Applicants respectfully submit that claims 12 and 23 as well as claims 13-15, 17-22, and 24-25 that depend therefrom are in condition for allowance. Applicants respectfully request withdrawal of the 35 U.S.C. § 112 rejection thereof.

Rejections based on 35 U.S.C. § 103 over Rosenfeld in view of Shen

Claims 1-15, 17-22 and 29-34 were rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenfeld, et al. U.S. Patent No. 6,804,656 (hereinafter "Rosenfeld") in view of Shen, Pre-Grant U.S. Publication No. 2003/0212580 (hereinafter "Shen"). As the Rosenfeld and Shen references, either alone or in combination, fail to teach or suggest all of the features of the rejected claims, as amended herein, Applicants respectfully overcome this rejection, as hereinafter set forth.

Independent Claim 1

Independent claim 1 recites a system for analyzing clinically related data. Independent claim 1 has been amended to further recite that the inference engine selectively

performs a comparative analysis of a key performance indicator of clinically related data against a knowledge base. A key performance indicator is representative of a financial, operational, or clinical metric for the operation of a clinical facility or organization. As such, the key performance indicators provide an overview of significant financial, operational, and clinical metrics required to effectively run a hospital or other facility. *Applicants' Specification* at ¶ [0016]. Additionally, independent claim 1 has been amended to more clearly recite that quantifying an opportunity for improvement when the altered guideline or policy is utilized in the clinical facility or organization is not an optional step.

In contrast, Rosenfeld describes providing continuous, expert network critical care services from remote locations. By Rosenfeld, a command center is provided at a remote location at which a doctor is located. *Rosenfeld* at col. 4, lines 53-57. A group of intensive care units (ICU) at disparate locations are provided with cameras and monitoring equipment such that patient data and communications are established between the command center and each of the ICUs. *Id.* at col. 4, lines 57-65. Clinical data is transmitted to the command center to allow the doctor to monitor and manage multiple patients at disparate ICUs from a single location. *Id.* at col. 5, lines 10-13. The clinical information is also submitted to a relational database that includes standardized guidelines for patient care, algorithms to support the intensive care regimen, order writing software, and knowledge-based algorithms that key the doctor to engage in preventative actions based on a patient's clinical information. *Id.* at col. 5, lines 13-24. Thus, a single doctor is able to manage multiple patients at various locations by being provided with the clinical information at a single location and is assisted in identifying issues by algorithms that analyze the clinical data transmitted from the patients' ICUs. *Id.* at col. 13, lines 36-43.

As such, Rosenfeld does not teach or suggest all of the elements of Applicants' independent claim 1. Rosenfeld does not describe key performance indicators as recited by claim 1. Rather, Rosenfeld describes assessing a patient's condition by comparing diagnostic data from the patient such as, the patient's heart rate or body temperature, with a diagnostic algorithm. *Rosenfeld* at col. 43, lines 11-53. The diagnostic data is not equivalent to the key performance indicator recited by Applicants' claim 1. The diagnostic data merely indicates characteristics of a patient's condition and does not describe financial, operational, or clinical metrics of a clinical facility or organization.

The Office Action also indicates that Rosenfeld does not disclose the comparative analysis projecting a facility-wide outcome, predicting an operational effect of altering a guideline or policy, or quantifying an opportunity for improvement when the altered guideline or policy is implemented as recited by independent claim1. The Office Action cites Shen in support of these deficiencies of Rosenfeld, however Applicants respectfully submit that Shen fails to cure these deficiencies of Rosenfeld.

Shen describes management of information flow and workflow in medical imaging services. *Shen* at ¶ [0037]. By Shen, various data items are collected throughout a patient's course of treatment by a medical imaging facility. *See id. generally.* A performance metrics module manipulates the data to calculate various flow metrics related to workflow and information flow to provide objective statistics that are useable to analyze the interaction of the workflow process with the information flow process. *Id.* at ¶ [0045]. An analysis tools module is also provided to perform practical and business performance analysis of the overall processes. *Id.* at ¶ [0046]. Using these modules, outcome metrics for performance measurements are generated such that diagnostic, clinical, service, and financial outcomes for the medical imaging

facility can be quantified and analyzed. *Id.* at ¶¶ [0071]-[0076]. Further, risk assessment and utilization assessments of testing procedures can also be quantified. *Id.* at ¶¶ [0059] and [0102].

Shen also describes that organizational benchmarks and goals may be changed such that the changed goals and the effects thereof may be compared to the collected data. *Id.* at ¶ [0109]. Organizational process analysis is also described as allowing simulation and prediction of modified process outcomes with the new organizational goals. *Id.* at ¶ [0133].

As such, Shen fails to teach or suggest key performance indicators as recited by independent claim 1 and described above. Shen describes tracking a multitude of different data sets, however none are described as being a key indicator or as providing an overview of significant financial, operational, or clinical metrics required to effectively run a facility. Further, Shen does not describe using such a key performance indicator of clinically related data in a comparative analysis against a knowledge base to project a facility-wide outcome, as recited by claim 1.

Independent claim 1 recites that the comparative analysis predicts an operational effect of altering a guideline or a policy currently in use by a facility and that opportunities for improvement that might result from such an alteration are quantified. As such, independent claim 1 describes altering a *guideline or policy* of the facility. Guidelines and policies are rules or principles that guide the course of action of the facility. In contrast, Shen describes comparing collected data with benchmarks and organizational goals and defines benchmarks and organizational goals as *potential or optimal targets*. *Shen* at ¶ [0109]. A target is merely an endpoint or a goal while a guideline or policy guides the course of action of the facility. Further, comparing data based on a changed endpoint merely indicates whether the endpoint is reached or not. In contrast, comparing data against a knowledge base and projecting a facility-wide

outcome of altering a guideline or policy describes the paths that are taken and the endpoints that may be attainable based on the new paths. Thus, the benchmarks and organizational goals of Shen are not equivalent to the guidelines and policies of Applicants' claim 1, and the comparisons described by Shen are also not equivalent to those of claim 1, as amended herein.

Following this, the projections described by Shen cannot describe projecting facility-wide outcomes that predict the operational effect of altering a guideline or policy as recited by claim 1. Under Shen, a projection of data is merely an extrapolation of the data based on an identified or changed target. *See Shen* at ¶ [0116]. Conversely, the projecting described by Applicants' claim 1 is based on an altered guideline or policy which is different from a goal as used in Shen.

Additionally, Shen describes enabling "organizational process analysis such as ... simulation and prediction of modified process outcomes with new organizational goals..." *Shen* at ¶ [0133]. Shen also describes enabling "cycle analysis, such as ... simulation of outcomes comparing with benchmarks or organizational projected goals with modification of current steps of processes." *Id.* at ¶ [0134]. Applicants respectfully submit that this description is unclear and as such is not enabling. "The disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation." MPEP § 2121.01.

The above description is unclear as to what is being predicted and how. For example, Applicants are unclear as to whether the simulation and prediction are based on the outcomes of modified processes or if it is based on new organizational goals causing the process outcomes to be modified. Applicants are also unclear as to what is being compared by the cycle

analysis. Additionally, Applicants submit that the above two references are the only description of simulation or prediction found by Applicants in the entirety of the Shen reference. Further, Shen does not provide any other details regarding how such a simulation or prediction is completed. As such, Applicants respectfully submit that the Shen reference does not provide an enabling disclosure of simulation or prediction and, thus, does not describe projecting a facility-wide outcome that predicts an operational effect of altering a guideline or policy being used in a clinical facility or organization based on a comparative analysis, and quantifying an opportunity for improvement when the altered guideline or policy is utilized in the clinical facility or organization as recited by Applicants' independent claim 1.

Independent Claim 12

Independent claim 12, as currently amended, recites computer-readable media having computer-executable instructions embodied thereon that, when executed, perform a method of analyzing clinically related data. Independent claim 12 includes one or more similar features to those of independent claim 1, such as selectively performing a comparative analysis, projecting a facility-wide outcome that predicts operational effects of altering a guideline or policy, as well as quantifying opportunities for improvement that result from implementing the altered guideline or policy. As such, the remarks provided above with respect to independent claim 1 apply equally to independent claim 12.

Independent claim 12 has also been amended to recite the clinically related data includes a data set that has been processed to generate multidimensional extensions of the raw data. *See Applicants' Specification* at ¶¶ [0001] and [0017], and U.S. Provisional Patent Application 60/498,283, incorporated by reference. Rosenfeld and Shen do not describe data or

using data that has been processed to generate multidimensional extensions of the raw data as recited by amended claim 12. Multidimensional data includes raw data that is enhanced to extend the data into logical structures reflecting meaningful groupings of the data not present in the raw data. *See* U.S. Provisional Patent Application 60/498,283 at ¶ [0005].

Independent claim 12 has been further amended to recite that an indication of a key performance indicator that is most significant to a user is provided and that an alert is generated that notifies a user when the user's actions are in violation of a guideline or policy of the clinical facility or organization. *See Applicants' Specification* at ¶¶ [0016] and [0022]. Rosenfeld and Shen as described above do not describe key performance indicators and thus cannot describe providing an indication to a user of a most significant key performance indicator. Also as described above, neither Rosenfeld nor Shen describe guidelines or policies as recited by Applicants' claim and, as such, do not describe generating an alert to notify a user that their actions are in violation of such a guideline.

Independent Claim 29

Independent claim 29, as currently amended, recites one or more similar features to those of independent claims 1 and 12 described above, and as such, the remarks provided above with respect to independent claims 1 and 12 apply equally to independent claim 29.

As such, it is respectfully submitted that Rosenfeld and Shen, either alone or in combination, fail to teach or suggest all of the claim features of independent claims 1, 12, and 29. Accordingly, Applicants submit that claims 1, 12, and 29 are not obvious over Rosenfeld in view of Shen. Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of independent claims 1, 12, and 29. Claims 1, 12 and 29 are believed to be in condition for allowance and such favorable action is hereby respectfully requested.

Claims 2-4, 6-11, 13-15, 17-22, and 30-34 depend, either directly or indirectly, from independent claims 1, 12, and 29. Thus, Applicants respectfully submit that Rosenfeld and Shen, either alone or in combination, fail to teach or suggest all of the features of dependent claims 2-4, 6-11, 13-15, 17-22, and 30-34 for at least the above-cited reasons. Accordingly, Applicants respectfully submit that dependent claims 2-4, 6-11, 13-15, 17-22, and 30-34 are not obvious over Rosenfeld in view of Shen, and request withdrawal of the 35 U.S.C. § 103(a) rejection thereof.

Rejections based on 35 U.S.C. § 103 over Shen

Claims 23-25 were rejected under 35 U.S.C. 103(a) as being unpatentable over Shen. As the Shen reference fails to teach or suggest all of the features of the rejected claims, as amended herein, Applicants respectfully overcome this rejection, as hereinafter set forth.

Independent Claim 23

Independent claim 23, as currently amended, recites a computer-implemented method of generating an analytic report. Independent claim 23 includes similar features to those described above with respect to independent claims 1, 12, and 29 such as clinically related data that includes data elements with multidimensional extensions of the data, performing a comparative analysis of the clinically related data against a selected guideline, policy or procedure contained within a knowledge base, and using an altered guideline, policy or procedure and the clinically related data to perform a predictive analysis that projects an operational, financial, or other facility-wide outcome and that predicts an operational effect of implementing the altered guideline, policy, or procedure in a clinical facility or organization.

Shen does not teach or suggest all of the features of independent claim 23 for at least the above-noted reasons provided with respect to independent claims 1, 12, and 29. For

example, Shen does not teach or suggest data with multidimensional extensions, performing a comparative analysis of the clinically related data against a guideline or policy, and projecting or predicting based on an altered guideline or policy.

Additionally, Shen does not describe updating the clinically related data following an implementation of an altered guideline or policy as recited by claim 23. As described above, Shen does not describe altering a guideline or policy and as such cannot describe updating data following such an implementation.

For at least the above reasons, Applicants respectfully submit that Shen fails to teach or suggest all of the claim features of independent claim 23. Accordingly, Applicants submit that claim 23 is not obvious over Shen. Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of independent claim 23. Claim 23 is believed to be in condition for allowance and such favorable action is hereby respectfully requested.

Claims 24-25 depend, either directly or indirectly, from independent claim 23. Thus, Applicants respectfully submit that Shen fails to teach or suggest all of the features of dependent claims 24-25 for at least the above-cited reasons. Accordingly, Applicants respectfully submit that dependent claims 24 and 25 are not obvious over Shen, and request withdrawal of the 35 U.S.C. § 103(a) rejection thereof.

CONCLUSION

For at least the reasons stated above, claims 1-4, 6-15, 17-25, and 29-34 are now in condition for allowance. Applicants respectfully request withdrawal of the pending rejections and allowance of the claims. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned – 816-5592564 or areed@shb.com (such communication via email is herein expressly granted) – to resolve the same. It is believed that no fee is due, however, the Commissioner is hereby authorized to charge any amount required to Deposit Account No. 19-2112.

Respectfully submitted,

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